

### REMARKS/ARGUMENT

Claims 22, 24-26, 30 and 39-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Babcock US 2001/0053791. The Examiner concedes that Babcock does not teach that at least 90 vol% of the particles have diameters greater than 10  $\mu\text{m}$ , as required by independent claim 22. However the Examiner apparently reasons that Babcock teaches spray drying to form a solid amorphous dispersion of particles from 1  $\mu\text{m}$  to 200  $\mu\text{m}$  in diameter, that it would have been obvious for one of ordinary skill in the art to modify the process parameters to achieve the claimed particle size of greater than 10  $\mu\text{m}$  in diameter, and that one would be motivated to do so because particle size adjustment amounts to routine experimentation and forming a composition wherein at least 90% of the particles have diameters of greater than 10  $\mu\text{m}$  is an obvious variant of the "teachings of the references" [sic]. This rejection is respectfully traversed.

Applicants note that while it may be true that a person of ordinary skill in the art is capable of adjusting the process conditions and equipment to obtain particles wherein at least 90 vol% of the particles have diameters greater than 10  $\mu\text{m}$ , the Examiner does not articulate any reasons as to why one of ordinary skill would be motivated to do so. Such articulation is required in an obviousness analysis. *KSR Int'l. Co. v Teleflex, Inc.*, 82 USPQ 2d 1385 (Sup Ct 2007).

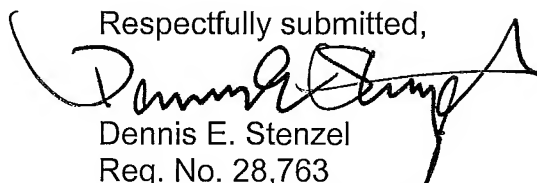
The Examiner also contends that the claim limitation of at least 90 vol% of the particles having diameters greater than 10  $\mu\text{m}$  would have been obvious unless there is evidence of criticality or unexpected results. The instant specification indeed does describe the criticality and unexpected results obtained by this feature of the invention in paragraph [0003] of published application US 2004/0194338. Such compositions of such particles have improved flow characteristics and collection efficiencies. These advantages are not taught by Babcock.

The remaining claims all ultimately depend from claim 22, and are therefore likewise not rendered obvious by Babcock.

Claims 22, 24-25, 30 and 39-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Albano US 6,350,786, the Examiner contending that Albano teaches a spray drying process wherein 90% particles are in the size range of 50-400  $\mu\text{m}$  and apparently pointing to Examples 4-12 and 15-16. However, it is noted that those Examples make the particles by a milling process, not a spray drying process, as claimed in independent claim 22. Albano at column 10, lines 16-31. Thus, Albano does not teach a spray drying process wherein at least 90 vol% of the particles have diameters greater than 10  $\mu\text{m}$ , as claimed. Without more, Albano does not render the claims in question obvious.

Claim 26 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Albano in view of Martin US 4,344,934, the Examiner contending that Martin teaches the drugs listed in claim 26. In response, claim 22 is not rendered obvious by Albano for the reasons stated above. Claim 26 depends from claim 22 and so incorporates the same limitations as claim 22; it is therefore likewise not rendered obvious by Albano. And although Martin discloses spray drying the drug griseofulvin, it is silent as to the particle size of the resulting composition. This rejection is therefore without merit.

For the reasons stated, early and favorable reconsideration is respectfully solicited.

Respectfully submitted,  
  
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